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COVID-19 long-acting antibodies discovered by Vanderbilt University Medical Center move to phase 3 clinical trials

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On Oct. 9, AstraZeneca announced it received support from the U.S. government for the development and supply of AZD7442 under an agreement with the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, and the Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense.

Antibodies are produced by white blood cells in response to infection. During the past 25 years, James Crowe Jr., MD, and colleagues in the Vanderbilt Vaccine Center have pioneered techniques for isolating human “monoclonal” antibodies that can neutralize a host of pathogenic viruses with a laser-like focus.

The two antibodies that make up AZD7442 were isolated by the VUMC team from the blood of a couple from Wuhan, China, who were diagnosed with COVID-19 after traveling to Toronto, Canada, in late January. According to the paper Crowe and colleagues published in the journal *Nature* in July, alongside AstraZeneca researchers, the two neutralizing antibodies, COV2-2196 and COV2-2130, can bind simultaneously and neutralize wild-type SARS-CoV-2 virus in a synergistic manner.

The antibodies were among six that were licensed to AstraZeneca in June for advancement into clinical development.

“We are excited about the progression of these antibodies into efficacy testing. In this collaboration, our VUMC team isolated the antibodies and worked with AstraZeneca to evaluate the most potent ones to take forward, before handing over to AstraZeneca for the engineering, manufacturing and clinical development,” said Crowe.

AZD7442 is among several antibody treatments being tested clinically for their ability to prevent or treat infection by the SARS-CoV-2 virus, which causes COVID-19.

AstraZeneca optimized the antibodies in AZD7442 using its proprietary half-life extension technology to extend the antibodies’ duration of action (the amount of time that the antibodies remain in the body). The goal is to provide protection against SARS-CoV-2 infection lasting for six to 12 months following a single administration, AstraZeneca announced. The company plans to evaluate the long-acting antibody combination in different settings, including prophylaxis, outpatient treatment and hospitalization.

Delivered by intramuscular injection or IV infusion, long-acting antibody treatments may be particularly beneficial for people who are elderly or immune-compromised, are at particularly high risk of contracting COVID-19 or are receiving medical treatments that preclude them from receiving a COVID-19 vaccine.

Use of AZD7442 to prevent COVID-19 is dependent on the U.S. Food and Drug Administration determining it is safe and effective, based upon the outcome of the two phase 3 clinical trials that are part of the agreement.

One phase 3 clinical trial will evaluate the safety and efficacy of AZD7442 to provide long-lasting protection in approximately 5,000 volunteers. Another 1,100 volunteers will be enrolled in a separate phase 3 trial to evaluate whether AZD7442 can help prevent infection in people who have been exposed to COVID-19.

AstraZeneca is also planning phase 2 and phase 3 trials to evaluate AZD7442 in approximately 4,000 patients for the treatment of COVID-19. The company will provide further details at a later time.